STATE OF MISSOURI MISSOURI BOARD OF PHARMACY

IN RE:)		
)		
IDOWA A. AJIBOLA)		
9944 W. Florissant)	Complaint l	No. 2017-003495
St. Louis MO 63136)		
Permit No. 2000148442		ì		

SETTLEMENT AGREEMENT

COME NOW Idowa A. Ajibola ("Respondent" or "Licensee") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's license to practice pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that he understands the various rights and privileges afforded him by law, including the right to a hearing of the charges against him; the right to appear and be represented by counsel; the right to have all charges against him proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against him; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against him and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against his license. Being aware of these rights provided it by operation of law, Respondent knowingly and

voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to him.

Respondent acknowledges that he has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's license.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's license to practice pharmacy, numbered 2000148442, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo

JOINT STIPULATION OF FACTS

- 1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo (2016)¹, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.
- Rehoboth Pharmacy, LLC, 9944 W. Florissant, St. Louis, MO 63136 (the "Pharmacy") is permitted by the Board under permit number 2007000836.
- At all times relevant herein, Idowa A. Ajibola was owner and permit holder of the
 Pharmacy and was employed as the pharmacist in charge ("PIC") of the Pharmacy.

¹ All statutory references are to the Revised Statutes of Missouri 2000, as amended, unless otherwise stated.

March 20, 2015 Inspection

4. On or about March 20, 2015, Board Inspector Bennie Dean visited the Pharmacy to conduct a routine inspection. An Observation Report was provided to Respondent detailing the violations observed by Inspector Dean on that date.

Failure to Maintain Pharmacy in Sanitary Condition

- During her March 20, 2015, inspection of the Pharmacy, Inspector Dean inspected the sanitary conditions of the Pharmacy.
- She observed that the tubing on the water dispenser was caked with dried medication and that the prescription area was cluttered and not clean and had no working counter space.
- She also observed sawdust, boxes and totes on the floor and dried paint on the counter.
 - 8. Missouri law requires:
 - (F) All pharmacies shall be maintained in a clean and sanitary condition at all times. Any procedures used in the dispensing, compounding and admixture of drugs or drug-related devices must be completed under clean and, when recommended, aseptic conditions.
 - 1. Appropriate sewage disposal and a hot and cold water supply within the pharmacy must be available.
 - 2. Appropriate housekeeping and sanitation of all areas where drugs are stored or dispensed must be maintained. 20 CSR § 2220-2.010(1)(F).
- 9. By having dried medication on the tubing of the water dispenser; a cluttered prescription area with no working counter space; and sawdust, boxes and totes on the floor and dried pain on the counter the Pharmacy was not in a clean or sanitary condition in violation of 20 CSR § 2220-2.010(1)(F).

Dispensing Errors

- 10. During her March 20, 2015, inspection of the Pharmacy, Inspector Dean also reviewed the Pharmacy's dispensing and prescriptions records.
 - 11. She noted dispensing errors for prescription nos. 23508 and 23520.
- 12. The Pharmacy's dispensing errors constitute a violation of professional trust and confidence under § 338.055.2(13), RSMo.

Failure to notify Board of remodeling plans

- During her March 20, 2015, inspection of the Pharmacy, Inspector Dean also observed that the Pharmacy was being remodeled.
 - 14. 20 CSR § 2220-2.020(4)(A) provides:
 - (A) Remodeling of a licensed pharmacy within an existing structure shall be deemed to have occurred when any change in the storage conditions of the Schedule II controlled substances is made or new connections to water/sewer resources are made or any changes in the overall physical security of drugs stored in the pharmacy as defined in 20 CSR 2220-2.010(1)(H) are made. Remodeling as defined within this section will not require the initiation of any change of location procedures. Satisfactory evidence of plans for any remodeling of a pharmacy must be provided to the board office thirty (30) days in advance of commencing such changes along with an affidavit showing any changes to the pharmacy physical plant and the projected completion date for any remodeling.
- 15. The Pharmacy violated 20 CSR § 2220-2.020(4)(A) by failing to give the Board its remodeling plans 30 days in advance of the remodeling commencement date along with an affidavit showing any changes to the Pharmacy physical plant and the projected completion date for the remodeling.

Return to stock violation

16. During her March 20, 2015, inspection of the Pharmacy, Inspector Dean also reviewed the Pharmacy's prescriptions that were returned to stock.

- 17. She observed that two prescriptions that had been returned to stock prescription nos. 711628 filled July 5, 2011 and 7116485 filled January 11, 2013 had expiration dates greater than 12 months from the dispensing dates.
 - 18. 20 CSR § 2220-3.040(3) states:
 - (3) Pharmacists and pharmacies may return to stock prescriptions that have not been received by the patient and shall delete the dispensing from the pharmacy's records and reverse the claim with the third party payor, if applicable. In order for a product to be returned to stock, it must have been stored at all times at the manufacturer's labeled storage requirements. The drug must be maintained in the patient container with the dispensing date, prescription number, and name of drug visible. The expiration date of the drug shall become the lesser of one (1) year from the dispensing date on the label or the manufacturer's original expiration date, if known. 20 CSR § 2220-3.040(3).
- 19. The Pharmacy violated 20 CSR § 2220-3.040(3) by maintaining returned to stock items with expiration dates greater than 12 months from the dispensing dates.

Outdated Drugs in Active Inventory and Misbranding

- 20. During her March 20, 2015, inspection of the Pharmacy, Inspector Dean also reviewed the Pharmacy's active inventory.
 - 21. She observed outdated drugs in the Pharmacy's active inventory.
 - 22. Missouri law states:
 - (6) Drugs and devices that are maintained as part of the pharmacy inventory or are being processed for dispensing or other distribution purposes must be physically separated at all times from articles, supplies or other drugs that are for employee personal use or that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances. Areas used for this type of drug storage must be clearly identified. 20 CSR § 2220-2.010(6).
- 23. By maintaining expired drugs in its active drug inventory, the Pharmacy was in violation of 20 CSR § 2220-2.010(6).

Misbranding

- 24. Inspector Dean also observed a manufacturer's stock bottle overfilled with 120 tablets at the Pharmacy.
- 25. Overfilling stock bottles constitutes misbranding and violates Missouri law, towit:

The following acts and the causing thereof within the state of Missouri are hereby prohibited:

- (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
- (2) the adulteration or misbranding of any food, drug, device, or cosmetic; §196.015(1)-(2), RSMo.
- 26. Misbranding of a drug under Missouri law is defined in § 196.100.1, RSMo, which states in pertinent part:
 - 1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.
 - 27. Federal law also prohibits misbranding, to-wit:
 - (a) The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.
 - (b) The adulteration or misbranding of any . . . drug . . . in interstate commerce. 21 U.S.C. § 331(a)-(b).
- 28. A legend drug is misbranded under 21 U.S.C. §352(a)(1) of the Federal Food, Drug and Cosmetic Act, as amended, "[i]f its labeling is false or misleading in any particular."

29. By overfilling stock bottles, the Pharmacy misbranded a legend drug product because the labels on the stock bottles were false and misleading in violation of §196.015, RSMo, §196.100, RSMo, 21 U.S.C. §352(a)(1), 21 U.S.C. §331(a)-(b).

March 2015 Compliance Notice

- 30. Upon completion of her March 20, 2015, inspection, Inspector Dean issued a Compliance Notice to the Pharmacy
- 31. The 2015 Compliance Notice requested a written response from the Pharmacy no later than April 1, 2015.
- 32. On or about April 13, 2015, the Board received a written response to the March 2015 Compliance Notice.
 - 33. The written response was signed by Respondent.
- 34. Regarding the Pharmacy's failure to advise the Board of its remodeling plans, the Pharmacy responded that it had been broken into and looted twice as a result of the events in Ferguson and that Respondent, his family and his staff were exposed to a dangerous environment. The response also stated that the Board and the BNDD were called to report the situation.
- 35. Regarding the Pharmacy's outdated drugs in active inventory, the Pharmacy responded that most of the outdated drugs were March 2015 waiting to be pulled and a few missed ones from the last check.
- 36. Regarding the misbranding by maintaining overfilled stock bottles, the Pharmacy responded that 20 tablets were added to the original bottle of 100 and stated "that will be corrected."

Corrective Action Plan

- 37. The Board sent correspondence dated June 1, 2015 to Respondent requesting that the Pharmacy submit a Corrective Action Plan identifying how the Pharmacy would address the compliance issues noted in the March 20, 2015 Observation Report and Compliance Notice.
- 38. On or about June 30, 2015, the Board received a Corrective Action Plan from the Pharmacy.
- 39. With regard to the unsanitary/unclean conditions, the Pharmacy stated it was cleaned and was made orderly and that it would conduct a weekly/monthly inspection of working areas and a Pharmacy self-assessment.
- 40. With regard to insufficient work space, the Pharmacy stated "counters now clean for work spaces" and that it would make sure the counter working area is free and paper clutter.
- 41. With regard to dispensing errors, the Pharmacy stated "error-proof system revisited, intensified protocol to minimize prescription errors."
- 42. With regard to outdated drugs in inventory, the Pharmacy stated "all outdated drugs removed from active inventory" and "sticker system employed."

July 7 and July 30, 2015 Remodeling Inspections

- 43. On or about July 7 and July 30, 2015, Board Inspector Bennie Dean visited the Pharmacy to conduct remodel inspections.
- 44. During her July 7, 2015, remodel inspection, Inspector Dean noticed that the roof was leaking and that there were no walls to the roof.
- 45. During her July 30, 2015 remodel inspection, Inspector Dean noticed that walls to the roof were not completed.

46. The Pharmacy was not in a clean or sanitary condition due to the leaking roof and the lack of walls in violation of 20 CSR § 2220-2.010(1)(F).

March 28, 2016 Inspection

47. On or about March 28, 2016, Inspector Dean returned to the Pharmacy to conduct a routine inspection. An Observation Report was provided to Respondent detailing the violations observed by Inspector Dean on that date.

Failure to Maintain Pharmacy in Sanitary Condition

- 48. During her March 28, 2016, inspection of the Pharmacy, Inspector Dean also observed that the prescription area was cluttered.
 - 49. The cluttered state of the prescription area violated 20 CSR § 2220-2.010(1)(F).
 - 50. This was a repeat violation.

Failure to maintain prescription drug delivery policies and procedures

- 51. During her March 28, 2016, inspection of the Pharmacy, Inspector Dean inspected the Pharmacy's prescription drug delivery policies and procedures.
- 52. She found that the Pharmacy failed to maintain written prescription drug delivery policies and procedures.
 - 53. 20 CSR 20 § 2220-2.013(1) requires:
 - (1) Every pharmacy delivering prescription drugs shall develop and implement written policies and procedures to ensure the safe and appropriate delivery of prescription drugs within the temperature requirements recommended by the manufacturer or the United States Pharmacopeia (USP). Except as otherwise provided herein, prescriptions filled by a Missouri licensed pharmacy may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy.
- 54. The Pharmacy's failure to develop and implement written policies and procedures regarding the delivery of prescription drugs was in violation of 20 CSR § 2220-2.013(1).

Outdated Drugs in Active Inventory

- 55. During her March 28, 2016, inspection, Inspector Dean also reviewed the Pharmacy's active inventory.
- 56. She noted that 20 drugs in the Pharmacy's active inventory had expired in 2016, 12 drugs had expired in 2015, two drugs had expired in 2014, and three drugs had expired in 2012.
- 57. Maintaining outdated drugs in the Pharmacy's active inventory violated 20 CSR § 2220-2.010(6).
 - 58. This was a repeat violation.

Dispensing Errors

- 59. During her March 28, 2016, inspection, Inspector Dean also reviewed the Pharmacy's dispensing and prescriptions records.
 - 60. She noted incorrect dispensing directions on the label of prescription no. 304796.
- 61. The Pharmacy's dispensing error constitutes a violation of professional trust and confidence under § 338.055.2(13), RSMo.

Failure to adequately secure controlled substances

- 62. During her March 28, 2016, inspection, Inspector Dean also reviewed the Pharmacy's storage of its controlled substances.
- 63. She observed that Schedule II controlled substances were not stored under lock.

 The keys were in the lock of the cabinet when she arrived at the Pharmacy.
- 64. Missouri law more specifically sets forth standards for the storage and holding for sale of controlled substances, to-wit:

- (1) Physical Security.
- (A) Controlled substances listed in Schedules I and II shall be stored in a securely locked, substantially constructed cabinet.

 19 CSR § 30-1.034(1)(A)
- 65. By having the key in the lock of the cabinet storing Schedule II controlled substances, the Pharmacy was in violation of 19 CSR § 30-1.034(1)(A).

March 2016 Compliance Notice

- 66. Upon completion of her March 28, 2016, inspection, Inspector Dean issued a Compliance Notice to the Pharmacy regarding the Pharmacy's outdated drugs in active inventory.
- 67. The March 2016 Compliance Notice requested a written response from the Pharmacy no later than April 8, 2015.
 - 68. On or about April 18, 2016, the Board received a written response.
- 69. The written response was signed by Respondent and stated, "I am going to work more effectively to clear these problems."

December 13, 2016 Inspection

70. On or about December 13, 2016, Board Inspectors Joe Dino and Dan Vandersand conducted a routine inspection of the Pharmacy. An Observation Report was provided to the Pharmacy detailing the violations observed by the Inspectors on that date.

Outdated Drugs in Active Inventory

- 71. During their December 13, 2016, inspection, the Inspectors reviewed the Pharmacy's active inventory.
 - 72. They noted that 21 drugs in the Pharmacy's active inventory had expired.
- 73. Maintaining outdated drugs in the Pharmacy's active inventory violated 20 CSR § 2220-2.010(6).

74. This was a repeat violation.

Dispensing Errors

- 75. During their December 13, 2016, inspection, the Inspectors also reviewed the Pharmacy's dispensing and prescriptions records.
 - 76. They noted the following dispensing errors:
 - A. prescription no. 305223, dispensed on October 12, 2016, was written as butalbital/asa/caffeine/codeine #3 and was dispensed as butalbital/APAP/caffeine/codeine #3;
 - B. prescription no. 305253 dispensed on November 5, 2016, was written as 1 bid and was dispensed as 1 po tid;
 - C. prescription no. 305257 dispensed on November 5, 2016, was written as 1 2 tsp qid prn and was dispensed as 1 tsp po qid prn;
 - D. prescription no. 305265 dispensed on November 10, 2016, was written as butalbital/asa/caffeine/codeine #3 and was dispensed as butalbital/APAP/caffeine/codeine #3; and
 - E. prescription no. 24451 dispensed on December 1, 2016, was written as 1-2 po q 4 pm p and was dispensed as 1 po q 4 pm p.
- 77. The Pharmacy's dispensing errors constitute a violation of professional trust and confidence under § 338.055.2(13), RSMo.
 - 78. Quality assurance reports were issued to the Pharmacy for the dispensing errors.

Failure to appropriately electronically record receipts of CSOS orders

- 79. During their December 13, 2016, inspection, the Inspectors determined that the Pharmacy was not creating records of its receipt of controlled substances from its supplier/s or electronically linking the records to the original order and archiving the records.
- 80. Specifically, the Pharmacy did not create such records or link the records for Schedule II controlled substance orders received on November 10, 2016, November 14, 2016, November 16, 2016, and November 23, 2016.
- 81. 21 CFR § 1305.22(g) states that when a purchaser receives a shipment of controlled substances, "the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
- 82. By failing to creating records of its receipt of controlled substances from its supplier/s and electronically linking them to the original order and archiving them, the Pharmacy was in violation of 21 CFR § 1305.22(g).

Controlled Substance Inventory Violation

- 83. During their December 13, 2016, inspection, the Inspectors also reviewed the Pharmacy's annual controlled substance inventory records.
- 84. They noted that the annual controlled substance inventory was taken July 11-13, 2016.

85. Missouri law states:

(D) A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken. 19 CSR § 30-1.042(1)(D).

86. The Pharmacy's failure to take its annual controlled substance inventory at the opening or closing of business was in violation of 19 CSR § 30-1.042(1)(D).

Failure to Maintain Pharmacy in Sanitary Condition

- 87. During their December 13, 2016, inspection, the Inspectors also observed that the pharmacy area was cluttered and had minimal counter space.
- 88. The cluttered state of the pharmacy area and minimal counter space of the Pharmacy violated 20 CSR § 2220-2.010(1)(F).
 - 89. This was a repeat violation.

December 2016 Compliance Notice

- 90. Upon completion of the December 13, 2016, inspection, Inspectors Dino and Vandersand issued a Compliance Notice to Respondent regarding the Pharmacy's two repeat violations.
- 91. The December 2016 Compliance Notice requested a written response from the Pharmacy no later than December 23, 2016.
- 92. On or about December 20, 2016, the Board received a written response to the December 2016 Compliance Notice.
- 93. The written response was signed by Respondent and stated, with regard to the outdated drugs in active inventory, "I am promising with my personal responsibility" that he would do "monthly checking rather than every other month."
- 94. With regard to the pharmacy area being cluttered with minimal counter space, Respondent responded that, "I am removing all unnecessary boxes, shelves, computers, etc., off the counter, unnecessary chairs, desks and boxes will be removed from pharmacy."

June 13, 2017 Inspection

95. On or about June 13, 2017, Inspectors Dean and Vandersand conducted another routine inspection of the Pharmacy. An Observation Report was provided to Respondent detailing the violations observed by the Inspectors on that date.

Temperature exceeded normal range

- 96. During their June 13, 2017, inspection, the Inspectors observed that the temperature in the Pharmacy was 85.1 degrees.
 - 97. Missouri law requires:
 - (G) The temperature of the facility where drugs are stored must be maintained thermostatically within temperature requirements as provided for by the manufacturer or the latest edition of the USP. Adequate refrigeration must be available to insure enough storage space for drugs requiring refrigeration or freezing and under temperatures adequate to maintain the drug products as recommended by the manufacturer, the latest edition of the USP, or both.

20 CSR § 2220-2.010(1)(G).

98. By maintaining the temperature at 85.1 degrees in June 2017, the Pharmacy violated 20 CSR § 2220-2.010(1)(G).

Outdated Drugs in Active Inventory

- 99. During their June 13, 2017, inspection, the Inspectors also reviewed the Pharmacy's active inventory.
 - 100. They noted that 30 over-the-counter items had expired.
- 101. Maintaining outdated drugs in the Pharmacy's active inventory of over-the-counter products violated 20 CSR § 2220-2.010(6).

Controlled substance prescription violations

- 102. During their June 13, 2017, inspection, the Inspectors also reviewed the Pharmacy's controlled substances prescriptions.
- 103. They observed that controlled substance prescription no. C-305468 was a facsimile prescription that had been prepopulated by the Pharmacy and that the Pharmacy had not maintained the date or time of the facsimile nor had it maintained the originating fax number for this prescription.

104. Federal law states:

(f) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

21 CFR § 1306.05(f)

- 105. Dispensing a controlled substance prescription prepopulated by the Pharmacy and not prepared by the practitioner violated 21 CFR § 1306.05(f).
 - 106. Missouri law requires:
 - (8) Any pharmacy receiving a controlled substance prescription transmitted by facsimile equipment shall maintain the facsimile copy of the prescription along with the date and time of transmission and the telephone number of the facsimile machine from which it originated, as a part of its original prescription records.

19 CSR § 30-1.048(8).

107. The Pharmacy's failure to maintain the date and time of faxed prescription no. C-305468 along with the telephone number of the facsimile machine from which it originated violated 19 CSR § 30-1.048(8).

Follow-up inspections

- 108. On July 17, July 25 and August 14, 2017, Inspector Dean went to the Pharmacy to follow-up on the temperature inside the Pharmacy.
- 109. While she was present on July 17, 2017, the Pharmacy's wall thermostat read 79 degrees and Inspector Dean's calibrated thermometer four-feet from the thermostat read 81.9 degrees.
- 110. The Pharmacy's thermometer on a shelf above the work area six feet into the Pharmacy read 80 degrees while Inspector Dean's calibrated thermometer six inches from the one on the Pharmacy's shelf read 82.7 degrees.
- 111. While she was present on July 25, 2017, the Pharmacy's wall thermostat read 77 degrees and Inspector Dean's calibrated thermometer four feet from the thermostat read 80 degrees.
- 112. Inspector Dean's calibrated thermometer placed in one of the Pharmacy's bays of drugs containing ophthalmic and otic preparations read 82.7 degrees.
- 113. The manufacturer package statement for the ophthalmic and offic preparations indicated that storage temperatures for the preparations were not to exceed 77 degrees.
- 114. While Inspector Dean was present on August 14, 2017, the Pharmacy's wall thermostat read 77 degrees and her calibrated thermometer four-feet from the thermostat read 81.8 degrees.
- 115. The Pharmacy's thermometer on a shelf above the work area six feet into the Pharmacy read 78 degrees while Inspector Dean's calibrated thermometer six inches from the Pharmacy's thermometer on the shelf read 82.7 degrees.

- 116. In the bay of drugs which contained ophthalmic and otic preparations for which the manufacturer recommended temperatures not to exceed 77 degrees, Inspector Dean's calibrated thermometer read 82.8 degrees.
- 117. A summary of the temperatures inside the Pharmacy in July and August 2017 are as follows:

Date Thermostat on wa		Chair 4 feet from thermostat	Shelf/therm.	In bay of drugs
7/17/17	79 degrees	81.9 degrees	82.7 degrees	
7/25/17	77 degrees	80.0 degrees	82.0 degrees	82 degrees
8/14/17	77 degrees	81.8 degrees	82.7 degrees	82.8 degrees

118. By maintaining the temperature above the manufacturer's recommended temperature for drug products in July and August 2017, the Pharmacy was in violation of 20 CSR § 2220-2.010(1)(G).

PIC Violations

- 119. All of the above-referenced violations committed by Respondent, the Pharmacy and any of its staff may be imputed to Respondent, who is ultimately charged with responsibility to ensure that the Pharmacy is operated in full compliance of all state and federal laws and regulations concerning the practice of pharmacy pursuant to § 338.210.5, RSMo, which states:
 - 5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.
- 120. As PIC, Respondent's failure to supervise pharmacy personnel to assure full compliance with state and federal pharmacy laws and regulations is in violation of 20 CSR § 2220-2.090(2)(E), (M), (N), (P), (R), (V), (W) and (Y) which states, in pertinent parts:

- (2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:
 - (E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of controlled substances are in compliance with state and federal laws;
 - (M) The pharmacy be kept in a clean and sanitary condition:
 - (N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;
 - (P) Policies and procedures are in force to insure safety for the public concerning any action by pharmacy staff members or within the pharmacy physical plant;
 - (R) Security is sufficient to insure the safety and integrity of all legend drugs located in the pharmacy;
 - (V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items;
 - (W) Assure full compliance with all state and federal drug laws and rules:
 - (X) Compliance with state and federal requirements concerning drug samples;
- 121. As PIC of the Pharmacy, Respondent's conduct, herein described, is in violation of 20 CSR § 2220-2.090. Further, pursuant to §338.210.5, RSMo, Respondent is responsible and deemed liable for all violations of the pharmacy and its staff herein described.

JOINT CONCLUSIONS OF LAW

- 122. Respondent's conduct is cause for disciplinary action against his license to practice pharmacy under § 338.055.2(5), (6), (13), (15) and (16), RSMo, which provides:
 - 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
 - (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
 - (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
 - (13) Violation of any professional trust or confidence;
 - (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;
 - (16) The intentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed by written or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription; provided, however, that nothing contained herein shall prohibit a pharmacist from substituting or changing the brand of any drug as provided under section 338.056, and any such substituting or changing of the brand of any drug as provided for in section 338.056 shall not be deemed unprofessional or dishonorable conduct unless a violation of section 338.056 occurs.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.1, RSMo:

A. Respondent's permit numbered 2000148442shall be placed on **PROBATION** for a period of **THREE** (3) **YEARS** ("disciplinary period"). The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

The following terms apply for the entire disciplinary period.

- Respondent shall comply with all applicable provisions of Chapter 338, Chapter 195, Chapter 196 and all applicable federal and state pharmacy/drug laws and regulations and all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
- 2. Respondent shall not serve as pharmacist-in-charge or manager-in-charge of any entity licensed or regulated by the Board except as noted below, or as a preceptor for pharmacy interns or as a teaching member of any school or college of pharmacy. Additionally, Respondent shall not serve as a consultant required by a Board disciplinary order for any pharmacy/drug distributor. The Respondent may be pharmacist-in-charge at permit number 2007000836.
- 3. Respondent shall keep the Board apprised of his current home, electronic mail (e-mail) and work addresses and telephone numbers. Respondent shall notify the Board of any change in Respondent's employer or Respondent's home or work address within ten (10) days of such change in a manner approved by the Board. For employer/work changes, Respondent's notification shall include the reasons for the change. If at any time Respondent is employed by a temporary employment agency or maintains employment that requires frequent daily or weekly changes of work location she must provide the Board a list of locations worked if requested by the Board or Board's representative.
- 4. If Respondent's license expires or becomes void/invalid, upon renewal or reapplication, Respondent's license shall be subject to all terms and conditions of discipline not previously satisfied, including any remaining suspension/probationary period.
- 5. Respondent shall cooperate with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of this Settlement Agreement. Respondent shall make himself available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings shall be at the Board's discretion and may occur periodically during the disciplinary period.

- Respondent shall respond to any written inquiry of the Board and provide any requested documentation/records within three (3) days of receipt of a written request from the Board or the Board's authorized designee, or as otherwise requested by the Board/Board designee.
- 7. If requested by the Board, Respondent shall submit to a criminal history background check via the Board's approved vendor at Respondent's cost. Unless otherwise directed by the Board, Respondent shall submit the required fingerprints and undergo the requested criminal history background check within ten (10) days of the Board's request.
- 8. Respondent shall submit to any drug, alcohol or urinalysis testing requested by the Board, at Respondent's cost. Testing may be conducted on any human sample, including, but not necessarily limited to, urine, blood, breath, hair, nails, skin or saliva. The timing, manner and scheduling for testing is within the Board's sole discretion.
- 9. Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:
 - a. Any arrest or issuance of a criminal complaint;
 - Any municipal/local arrest, citation or complaint relating to drugs, theft, shoplifting, burglary, possession of drug paraphernalia, driving or operating a motor vehicle under the influence/while intoxicated or illegally possessing, selling or purchasing alcohol, any drug or drug paraphernalia;
 - A finding or plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment, including, but not limited to, any deferred or diverted adjudication, order or agreement;
 - d. A conviction of any crime, including, but not limited to, any Suspended Imposition of Sentence ("SIS") or Suspended Execution of Sentence ("SES"):
 - e. A finding by a court that Respondent has violated any term of his criminal probation/parole;
 - f. Any discipline, citation, or other administrative action filed or taken against Respondent by any state board/committee of pharmacy, or any other state or federal agency.

Failure to timely report any of the foregoing occurrences shall be considered a disciplinary violation.

10. If Respondent is currently or begins serving any period of criminal probation/parole, Respondent shall provide the name of his probation/parole officer to the Board, in writing, within ten (10) days of the effective date of this Agreement or within ten (10) days of the designation of a probation/parole officer. If Respondent's probation/parole officer is changed for any reason, Respondent shall submit the name of the replacement

officer to the Board within ten (10) days of the change/modification. Respondent shall execute a release authorizing his probation or parole officer to provide to the Board any information relating to Respondent's probation or parole. Respondent shall maintain the release in effect and shall provide an updated release if requested by the Board.

- 11. Respondent shall file a "Disciplinary Compliance Report" with the Board in a form/manner approved by the Board. The Disciplinary Compliance Report shall be due by January 1 and July 1 of each calendar year. Respondent's final Disciplinary Compliance Report shall be filed no later than ninety (90) days before the end of the probationary period.
- 12. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.
- The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

NOTICE TO EMPLOYERS

- 14. If applicable, Respondent shall notify any employer of the employer's need to apply for and receive the necessary state (misdemeanor/felony) and federal (felony) waivers from the Bureau of Narcotics and Dangerous Drugs and the Drug Enforcement Administration in order to be employed within a facility that maintains state or federal registrations for the purpose of storing, distributing or dispensing controlled substances.
- 15. Except as otherwise provided herein, "Employment" within the meaning of this Agreement shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist in or any position for which a pharmacist license, pharmacy intern license or pharmacy technician registration is a requirement or criterion for employment in, regardless of whether Respondent is an employee, independent contractor, volunteer, instructor or consultant. "Employment" shall also include any entity where legend drugs are stored, sold, dispensed or distributed.
- 16. Respondent shall notify any current or future employers of this action by providing a copy of this Settlement Agreement to the pharmacist-in-charge or manager-in-charge of any pharmacy or drug distributorship where Respondent is employed, on or before the effective date of discipline or prior to accepting any offer of employment.
 - a. If Respondent is not or will not be employed by a pharmacy or drug distributor, the notice shall be provided to Respondent's direct supervisor at Respondent's current/prospective place of employment, as defined herein, within the timeframes required by this section.
 - b. For purposes of this Agreement, a pharmacy shall also include, but is not limited to, any location providing pharmacy services for inpatients of a licensed hospital or residents of a long term care facility.

- 17. Respondent shall cause the pharmacist-in-charge, manager-in-charge or supervisor of any employer to sign a written acknowledgment on a form approved by the Board indicating that he/she has received and reviewed the Settlement Agreement and the terms and conditions imposed thereby. The written acknowledgement shall be signed and dated by the applicable pharmacist-in-charge, manager-in-charge or supervisor and shall be submitted to the Board by Respondent for verification within ten (10) days of the dated signature. Respondent shall be responsible for ensuring the required signed acknowledgments are timely submitted to the Board.
- 18. If at any time Respondent is employed by a temporary employment agency, Respondent must provide each employment agency a copy of this Settlement Agreement prior to being assigned to a temporary employment site. Respondent shall also provide a copy of the Settlement Agreement to each pharmacist-in-charge or manager-in-charge of each pharmacy or drug distributor where Respondent is assigned to work. If the pharmacist-in-charge or manager-in-charge is not present at the employment site, a copy of the Settlement Agreement shall be left at the applicable site for the pharmacist-in-charge/manager-in-charge to review. Respondent shall provide an accurate listing of all employment/work sites where Respondent has been assigned if requested by the Board or the Board's authorized designee.
- 19. Licensee shall execute any release or provide any authorization necessary for the Board to obtain records of Respondent's employment during the period covered by this Settlement Agreement.

CONTINUING EDUCATION

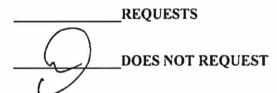
- 20. Within three (3) months of the effective date of this Settlement Agreement, Respondent shall take and pass the Board approved Pharmacy Practice Guide Continuing Education Examination, if available. Respondent shall register and complete the required examination via the Board's website or as otherwise requested by the Board.
- 21. Respondent shall take a minimum of 6.0 continuing education (0.60 CEUs) hours in pharmacy law during each biennial pharmacist renewal period that is completed while Respondent is on discipline. The continuing education required by this section shall comply with 20 CSR 2220-7.080 and may be used to satisfy the licensee's biennial continuing education requirement. Proof of compliance with the continuing education requirements of this section shall be submitted to the Board on or before October 31st of each biennial pharmacist renewal period.
- B. Upon the expiration of said discipline, Respondent's license as a pharmacist in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that Respondent has violated any term or condition of this Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate

and set aside the discipline imposed herein and may suspend, revoke or otherwise lawfully discipline Respondent.

- C. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.
- D. No order shall be entered by the Board pursuant to the preceding paragraph of this Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.
- E. The terms of this Settlement Agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement not any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.
- F. Respondent, together with his heirs and assigns, and his attorneys, do hereby waive and release, acquit and forever discharge the Board, its respective members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and

attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,



THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT

IDOWA A. AJIBOLA

By:

Kimberly Grinston Executive Director

PETITIONER

PHARMACY

MISSOURI BOARD OF

NEWMAN, COMLEY & RUTH P.C.

#48675

By:

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